NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE SCHERING-PLOUGH CORP. INTRON/TEMODAR CONSUMER CLASS ACTION,	: : :	Master File No. 2:06-cv-5774 (SRC)

OPINION

CHESLER, U.S.D.J.

This matter comes before the Court on the motion to dismiss the Amended Civil Consumer Class Action Complaint filed by Plaintiff Angela Montgomery ("Plaintiff" or "Montgomery") on September 9, 2009 (hereinafter referred to as the "Montgomery Amended Complaint" to avoid confusion with a separate amended complaint filed by other plaintiffs in this multidistrict litigation). [The motion to dismiss the Montgomery Amended Complaint has been filed at docket entry 219]. The moving Defendants are Schering-Plough Corporation, Schering Sales Corporation, Schering Corporation and Integrated Therapeutics Group, Inc. (collectively "Defendants" or "Schering"). Plaintiff has opposed the motion. For the reasons expressed below, the Court will grant the motion and dismiss the Montgomery Amended Complaint in its entirety.

I. BACKGROUND

This matter arises out of the allegedly fraudulent marketing practices employed by Schering with respect to the prescription drugs Intron-A, PEG-Intron, Rebetol and Temodar (collectively, the "Subject Drugs"). Intron-A, PEG-Intron and Rebetol were sold both individually and in combination with each other. Montgomery, a consumer of Rebetol and PEG-Intron prescribed in combination, was one of nine Plaintiffs named in the original Consolidated Class Action Complaint (the "Complaint") filed with this Court on December 1, 2006.[1] The Court dismissed the Complaint with leave to re-plead by Opinion and Order dated July 10, 2009. After that, two separate Amended Complaints were filed - one by four third-party payor Plaintiffs and another by Montgomery.[2] The Montgomery Amended Complaint is brought on behalf of a putative nationwide class of consumers of the Subject Drugs.[3] Although the Court had previously summarized the factual background of this action in its July 10, 2009 Opinion[4] concerning the sufficiency of the Complaint, the Montgomery Amended Complaint shifts the

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[1] The nine Plaintiffs named in the Complaint were: International Brotherhood of Teamsters Local No. 331 Health & Welfare Trust Fund, Heavy and General Laborers' Local Union 472/172 Welfare Fund, United American Insurance Company, Blue Cross Blue Shield of Alabama, Angela F. Montgomery, Harold Estelle, Beryl A'dare Bratton and Dorothy Bratton, and John Hutson, as putative personal representative of the Estate of John C. Hutson

[2] Schering, along with several individual Defendants additionally named in the third-party payor's Amended Complaint, also moved to dismiss that Amended Complaint. The Court has addressed that separately-filed motion in an accompanying but independent Opinion.

[3] The four other individual consumers who were named as Plaintiffs in the original Complaint have not joined in the Amended Complaint that is before the Court on the instant motion. Montgomery is the sole Named Plaintiff on the Montgomery Amended Complaint.

[4] In re Schering-Plough Corp. Intron/Temodar Consumer Class Action ("Schering I"), No. 06-5774, 2009 WL 2043604 (D.N.J. July 10, 2009).

focus to consumer plaintiffs, and of course, to Montgomery herself. The particular experience relating to Montgomery's purchase and use of two of the Subject Drugs as well as the different legal theories pursued on behalf of consumer plaintiffs call for a brief overview of the facts as they are set forth in the allegations of the Montgomery Amended Complaint.

Montgomery suffered from Hepatitis C, a viral infection affecting the liver. Though she was asymptomatic, Montgomery was concerned about the disease in light of her plans to marry and start a family. Thus, in 1999, she consulted with her family physician, who referred her to Dr. Jeffrey R. Willis of Digestive and Liver Disease Specialists in Norfolk, Virginia.[5] Tests he ordered in and around June 1999 confirmed that Montgomery remained asymptomatic, and so for various reasons in his professional opinion, Dr. Willis decided not to prescribe Montgomery a combination therapy consisting of Rebetol and Intron-A. He discussed this recommended course of no treatment with Montgomery in September 1999. Following that consultation, Montgomery continued routine follow-up testing of her liver enzymes, as Dr. Willis directed, but did not have any further discussion with him concerning treatment.

Then, on September 19, 2001 Montgomery was called in to see Dr. Willis for a follow-up visit. Although he noted that she continued to be clinically asymptomatic, that she did not show

[5] The Montgomery Amended Complaint alleges, somewhat inconsistently with the allegations regarding the place where Montgomery sought and received treatment, that at all relevant times Montgomery was a resident of Bellingham, Washington. The Court notes this only to provide the reader with some context to understand why Montgomery would be pursuing a cause of action under the State of Washington's consumer protection statute, discussed later in this Opinion. As expressly stated in their moving brief, Defendants concede for purposes of this motion that Washington law applies, and the Court is thus not faced with a choice of law question at this stage of the litigation.

evidence of decompensation[6] from her liver disease and that she still desired to become pregnant, Dr. Willis changed his mind as to how to approach treating Montgomery's illness. The Montgomery Amended Complaint alleges that at the September 2001 follow-up consultation, Dr. Willis "recommended treatment with the very same drugs he had previously indicated were contraindicated and inappropriate for Mrs. Montgomery's care and treatment." (MAC, ¶ 29.)[7]

Here, the Court must digress for a moment from the narrative of Plaintiff's treatment to sort out some confusion created by the Montgomery Amended Complaint's inconsistencies regarding what medications were the subject of Dr. Willis's advice, in 1999 and later in 2001, and what medication Dr. Willis considered appropriate for Montgomery's condition and ultimately prescribed to her. It alleges that, in 1999, Dr. Willis decided not to prescribe Montgomery the "Rebetron Combination Therapy (Rebetol/PEG-Intron)." (MAC, ¶ 23.) However, introductory paragraphs describing the drugs at issue identify Rebetron Combination Therapy as consisting of Rebetol and Intron A, not Rebetol and PEG-Intron, which form a different combination therapy altogether (termed the "PEG-Intron Combination Therapy" by the Montgomery Amended Complaint). (Id., ¶ 2.) Intron A and PEG-Intron are different forms of interferon, and PEG-Intron was not even on the market in 1999. (Id., ¶¶ 64-66.) In fact, the Amended Complaint states that in January 2001, the Food and Drug Administration ("FDA") approved PEG-Intron to treat Hepatitis C patients with compensated liver disease and in August

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[6] Decompensation is the failure of an organ to fulfill its function adequately. In the September 19, 2001 letter to Montgomery's primary physician summarizing the consultation, Dr. Willis provides as specific examples of liver decompensation "jaundice, ascites, encephalopathy, GI bleeding, [and] portal hypertension." (MAC, Ex. E.)

[7] Citations to the Montgomery Amended Complaint will be abbreviated as "MAC" followed by paragraph or exhibit number.

2001 approved the Rebetol/PEG-Intron combination therapy for this indication (Id., ¶¶ 66, 74.) The Court therefore draws the reasonable inference that the treatment discussed in 1999 involved Rebetol and/or Intron-A, but not PEG-Intron. Moreover, despite the assertion that the "same drugs" that Dr. Willis had rejected as unsuited to Montgomery's condition in 1999 were under consideration in 2001, the records attached to the Montgomery Amended Complaint and specifically referenced in paragraph 29 state that Dr. Willis recommended in 2001 that Montgomery receive pegylated interferon (PEG-Intron) not Intron A. (MAC, Ex. E.)[8]

Months after the follow-up consultation, Montgomery was prescribed PEG-Intron and Rebetol combination therapy. The Montgomery Amended Complaint specifically alleges that she "was prescribed and paid for both PEG-Intron and Rebetol (Rebetron Combination Therapy for the treatment of her asymptomatic Hepatitis C without compensated liver disease during the period of at least June 2002 through 2003.")[9] (MAC, ¶ 75.) Though Montgomery alleges that she began to pay for the drugs in or about June 2002, the records show that she did not commence treatment until sometime in the autumn of that year. (MAC, Ex. I.) Montgomery

[8] Throughout this Opinion, the Court at times refers to Montgomery's medical records, which as the explicit basis for many of Montgomery's allegations, are properly considered by the Court in adjudicating the instant motion. In re Burlington Coat Factory Secs. Litig., 114 F.3d 1410, 1426 (3d. Cir. 1997) ("document[s] integral to or explicitly relied upon in the complaint" may be considered on a motion to dismiss.). Indeed, various records are attached to the Montgomery Amended Complaint.

[9] The confusion seen throughout the Montgomery Amended Complaint as to which drugs were at issue in Montgomery's treatment is again evident in the allegations concerning which combination therapy Montgomery ultimately received. Compare MAC ¶¶ 5-6 (alleging she was prescribed "Rebetron Combination Therapy") with MAC ¶¶ 36-37 (alleging she was prescribed Rebetol/PEG-Intron). Because the medical records attached to the Montgomery Amended Complaint make clear that Montgomery ultimately received the Rebetol/PEG-Intron treatment, and not Rebetron, the Court will assume that the pleading's references to Montgomery's "Rebetron" purchases and prescriptions were made in error.

avers that at the time she was prescribed the drugs, they were only approved for patients with compensated liver disease. She asserts that she, in contrast, was healthy and did not need the treatment. Montgomery claims that, as a result of the off-label treatment recommended and prescribed by Dr. Willis, she endured many of the serious side effects of this combination therapy and lost weeks of work due to debilitating side effects. She does not specify which side effects she suffered, and the Court notes that her own medical records document that Dr. Willis discussed side effects with her, including the contraindication for pregnancy. (MAC, Ex. E.)

The Montgomery Amended Complaint attributes Dr. Willis's reconsidered opinion as to treatment to Schering's improper marketing of the Rebetol/PEG-Intron combination therapy. It avers that "Dr. Willis's new plan for Mrs. Montgomery's treatment for her asymptomatic Hepatitis C evidences that he was subjected to the marketing and sales scheme by Schering alleged in this Amended Complaint." (MAC, ¶ 30.) The Montgomery Amended Complaint bases this conclusion on several alleged facts: (1) Dr. Willis held a mistaken belief that ribavarin and interferon (generic terms for the Schering drugs) was the standard therapy for Montgomery's condition and this misunderstanding must have been the result of Schering's off-label promotion of Rebetol/PEG-Intron, as it was not yet approved by the FDA for cases of Hepatitis C with no compensated liver disease; (2) Dr. Willis did not supply Montgomery with the Mediation Guide, providing user instructions and warning of serious risks of use, as required by the FDA; (3) Dr. Willis prescribed the Rebetol/PEG-Intron combination therapy before sending her for two tests he had indicated would be necessary before prescribing the treatment; and (4) Dr. Willis and his patients were subjected to misleading promotion of the drugs by virtue of keeping a nurse on

staff identified as "DS" or "Diana S.", believed to be"Patient Care Consultant" ("PCC") provided by Schering for the ostensible purpose of helping patients with side effect management and injection training.

With regard to the kind of improper marketing tactics to which Montgomery alleges Dr. Willis must have been subjected at some point between his original treatment recommendation in 1999 and his revised advice in 2001, the Montgomery Amended Complaint relies heavily on the allegations made in other legal actions brought against Schering concerning off-label marketing of certain drugs, including the drugs that Montgomery was prescribed. In particular, it incorporates by reference the entire complaint in a civil qui tam action brought against Schering in the District of Massachusetts by three former Schering employees seeking relief on behalf of the federal and various state governments for losses incurred by paying claims made through healthcare programs such as Medicare. (MAC, Preamble and Ex. A.) It also incorporates the allegations made in a criminal information, to which Schering Sales Corporation pleaded guilty, charging that Schering subsidiary with criminal conspiracy to defraud the federal government by making false statements to the FDA in violation of the federal Food, Drug and Cosmetics Act ("FDCA"). (MAC, ¶¶ 99-101.) The Court need not, in this Opinion, go into detail about the kinds of wrongdoing charged by those other pleadings. It suffices for purposes of this Opinion that improper marketing alleged in the Montgomery Amended Complaint consisted of off-label promotion; some unspecified misrepresentations about the Subject Drugs made via Schering sales representatives and two Schering programs designed to provide patient support (the "Be In Charge" program) and to ensure uninterrupted access to medication (the "Access Assurance" program); the presence of a Schering-paid nurse on Dr. Willis's staff (the PCC identified as

D.S.); and a scheme of kickbacks, consisting of payments disguised as remunerations for things such as speaking engagements or participation in clinical trials.

Montgomery seeks relief for herself and on behalf of a putative class of consumers nationwide of the Subject Drugs. The Montgomery Amended Complaint contains five counts, asserting claims for (1) violation of the consumer protection statute of the state of Washington; (2) violation of the consumer protection statutes of the other 49 states, District of Columbia and Puerto Rico; (3) common law conspiracy; (4) aiding and abetting breach of fiduciary duty; and (5) unjust enrichment.

The Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d).

II. DISCUSSION

In their motion to dismiss, Defendants raise the threshold jurisdictional question of Montgomery's standing to bring this lawsuit. Specifically, they argue that the factual allegations of the Montgomery Amended Complaint, even if assumed to be true as they must be at the pleadings stage of litigation, do not demonstrate that Montgomery suffered any injury as a result of purchasing and taking Rebetol/PEG-Intron. Injury-in-fact is essential to a party's standing under Article III of the Constitution to bring a particular claim for relief. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 96-97 (1998); United Food and Commercial Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 551 (1996); Interfaith Cmty. Org. v. Honeywell Int'l, 399 F.3d 248, 254 (3d Cir. 2005). Moreover, because Article III standing is jurisdictional, the

Court has an independent obligation to satisfy itself that Montgomery has standing to sue. Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). This threshold matter must be addressed before reaching the question of whether her pleading states prima facie claims. Id. (citing Raines v. Byrd, 521 U.S. 811, 818 (1997)).

Defendants' position that Montgomery lacks Article III standing raises a question of whether this case may not proceed for jurisdictional defect. Thus, it implicates Federal Rule of Civil Procedure 12(b)(1). Id. at 810. The standard of review applicable to Rule 12(b)(1) motions, as set forth in the July 10, 2009 Opinion, will govern here. See Schering I, 2009 WL 2043604, at *6.

Article III of the Constitution limits the power of federal courts to "Cases" or "Controversies." Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-60 (1992). The Supreme Court has articulated what Article III standing entails:

> Over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"-an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of - the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. at 560 (internal quotations, alterations and citations omitted). In Lujan, the Supreme Court stressed the injury-in-fact requirement that the harm claimed be "particularized," or as it explained, that it affect the plaintiff personally. Id. at 561 n.1. "[T]he 'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be

himself among the injured." Id. at 563 (quoting Sierra Club v. Morton, 405 U.S. 727, 734-35 (1972)).

A plaintiff seeking redress in federal court bears the burden of establishing it has standing to sue. Id. at 561; Warth v. Seldin, 422 U.S. 490, 508 (1975). To do this, it must support each of the three elements enumerated above in the same manner required to sustain any other burden at the particular stage of litigation in which jurisdiction is challenged. Lujan, 504 U.S. at 561. Relevant to the instant motion, standing may be demonstrated at the pleading stage based upon the complaint's factual allegations of injury resulting from defendant's conduct. Id.

In assessing whether Montgomery has, by the allegations of the Montgomery Amended Complaint, established standing to sue, the Court will accordingly apply the standard of reviewing a complaint's sufficiency under Rule 8(a), as enunciated by the Supreme Court in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007) and Ashcroft v. Iqbal, 129 S.Ct. 1937 (2009). These cases held that viable complaints must be held to a plausibility standard. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 570. Under this standard, a complaint must contain sufficient factual allegations, which taken as true, raise a right to relief above the speculative level. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 589. While the complaint need not demonstrate that a defendant is *probably* liable for the wrongdoing, allegations that give rise to the mere *possibility* of unlawful conduct will not do. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 557.

The Court finds that the allegations of the Montgomery Amended Complaint adequately establish that Montgomery suffered an injury-in-fact, that is an invasion of a legally protected interest. She has alleged that she purchased the Subject Drugs and that she would not have done so had her doctor's professional judgment and behavior not been improperly influenced by

Schering's marketing scheme, which she more particularly alleges included bribing physicians to prescribe the drugs that Dr. Willis did in fact prescribe for her. Defendants, understandably guided by the Court's July 10, 2009 Opinion dismissing the original Complaint in this action, have argued that Plaintiff has not established cognizable injury because she has not alleged that the Rebetol and PEG-Intron she purchased were somehow inferior and therefore worth less than the price she paid for drugs. They underscore, specifically, that the Montgomery Amended Complaint does not aver that the drugs purchased by Montgomery were unsafe or ineffective. The Court's discussion in the July 10, 2009 Opinion as to viable theories of injury was, however, tailored to the claims brought under the Racketeering Influence Corrupt Organizations Act ("RICO"). In this case, Plaintiff does not pursue a RICO claim but rather claims a violation of her rights as defined by the Washington Consumer Protection Act, as well as various common law theories. The Court must therefore evaluate Montgomery's standing by examining whether an invasion of her legal interests as defined by the claims pled here has been adequately asserted in the Montgomery Amended Complaint.

The Washington statute provides relief for plaintiffs who have suffered injury to business or property as a result of an unfair or deceptive act or practice in trade or commerce. Mason v. Mortgage Am., Inc., 114 Wash.2d 842, 852 (Wash 1990) (en banc). The Supreme Court of Washington has held that very little is required to establish injury within the meaning of the state's Consumer Protection Act: "The injury element will be met if the consumer's property interest or money is diminished because of the unlawful conduct even if the expenses caused by the statutory violation are minimal." Id. at 854; see also Nordstrom v. Tampourlos, 107 Wash.2d. 735, 740 (Wash. 1987) (en banc) (holding that Consumer Protection Act's use of word

"injury" rather than "damages" indicates that it covers broad range of harm, including non-quantifiable losses such as goodwill). Having actually purchased Rebetol and PEG-Intron herself, Montgomery sufficiently states that she suffered concrete injury-in-fact.

This loss of her own money in purchasing Rebetol/PEG-Intron also suffices to state a injury-in-fact under her common law theories of relief of conspiracy, aiding and abetting breach of fiduciary duty and unjust enrichment. She is seeking to recover for her own purchases, made allegedly as a result of Schering's unlawful inducement to her doctor to alter his prescription decisions, interference with her and her doctor's fiduciary relationship and/or conspiracy with the doctor to cause her to purchase the allegedly unneeded combination therapy drugs. Had these wrongs not been committed, Montgomery's Amended Complaint avers, she would not have purchased drugs that, as an asymptomatic patient with no compensated liver disease, she did not need.[10] As to all these claims, she has stated a violation of her own legally protected interests, satisfying the concrete and particularized injury requirement of standing.

Injury-in-fact, however, is but one of the three essential components of Article III standing. Montgomery's standing to bring suit founders on her inability to establish any nexus between her purported injury - be it the needless purchase of the Rebetol/PEG-Intron, the side-effects she claims to have suffered and/or the lost work time - and the wrongful conduct in which Schering was allegedly engaged. She alleges that her prescribing doctor's shift from opining in

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[10] The Court notes that the cognizable interest constituting Plaintiff's asserted harm is the purchase itself, not Montgomery's desire not to purchase the drugs at a price artificially inflated as a result of the allegedly unlawful marketing practices. The latter would amount to a "fraud on the market" theory of injury, which the Court had rejected in the July 10, 2009 as viable under neither RICO nor New Jersey's consumer protection statute. See Schering I [cite]; see also Heindel

1999 that she was not an appropriate candidate for Rebetron (Rebetol and Intron-A) combination therapy to recommending, two years later, that she ought to consider treating her asymptomatic Hepatitis C with Rebetol/PEG-Intron combination therapy clearly must have been the result of Schering's marketing practices. The allegation, though quoted in the Background section of this Opinion, bears repeating: "Dr. Willis' new plan for Mrs. Montgomery's treatment for her asymptomatic Hepatitis C evidences that he was subjected to the marketing and sales scheme by Schering alleged in this Amended Complaint." (MAC, ¶ 30.) This allegation would, if supported, form the critical link between the averred harm Montgomery sustained in purchasing and taking Rebetol/PEG-Intron and the complained-of misconduct by Schering - as opposed to the action or conduct of some third party. The trouble is that the Montgomery Amended Complaint fails to provide any factual allegations that would support the conclusion.

For the most part, the allegations ostensibly offered as factual underpinnings are wholly inapposite. Plaintiff asserts that Dr. Willis held an erroneous belief (in Plaintiff's view) that Rebetol/PEG-Intron therapy was the medical standard for treatment patients such as Montgomery because he was exposed to "misleading statements" made by Schering in marketing the drug for off–label use. Apart from the equally reasonable inference that Dr. Willis may have come to such an understanding based on his own correct or incorrect reading of the available medical literature, based on information contained in the Compendia or even based on discussions with other medical professionals, the Court made it clear in the July 10, 2009 Opinion that off-label marketing is not inherently fraudulent. Even if Dr. Willis did form his opinion about Rebetol/PEG-Intron as appropriate to treat Montgomery's condition based on claims made by Schering sale representatives promoting the drugs for uses not approved by the FDA, this

assumption does not necessarily include the further assumption that the promotional claims were false. Indeed, to the extent Montgomery's claims for relief are at all based on mere off-label promotion, they fail for lack of injury-in-fact. In any event, nothing in the Montgomery Amended Complaint forges even a minimal connection between Schering's allegedly wrongful conduct and her purchase and use of the Rebetol/PEG-Intron based on Dr. Willis's prescription.

The attempt to establish standing is not resurrected by Plaintiff's theory that her relationship with Dr. Willis was co-opted by Schering's placement of a PCC nurse, identified only as "D.S." or "Diana S.," in his office. Montgomery's claim that the involvement of this nurse in her treatment was part of Schering's deceitful marketing scheme and somehow caused Dr. Willis to prescribe Rebetol/PEG-Intron to Montgomery is purely conclusory. Again, assuming that Diana S. was paid by Schering to provide patient support in matters such as injection training and side-effect management to those patients of Dr. Willis, including Montgomery, undergoing Rebetol/PEG-Intron combination therapy, there is no indication that Schering executed the alleged misrepresentations or kickbacks through this PCC. Nor is there any indication that false information was communicated directly to Montgomery through the Be In Charge and Access Assurance programs. In other words, Montgomery has failed to trace her purported injury to Schering's complained-of misconduct, either through Dr. Willis or based on a theory of direct exposure to the misconduct through the patient support services.

The other aspect of Schering's alleged unlawful conduct - providing doctors with straightforward bribes as well as payments disguised as legitimate remuneration to encourage them to write prescriptions for the Subject Drugs - is not even remotely tied to Montgomery's experience. The Montgomery Amended Complaint asserts that Schering paid doctors illegal

remunerations to prescribe Subject Drugs. (MAC, ¶ 70.) It noticeably lacks any allegation either directly accusing or even plausibly suggesting that Montgomery's doctor, Dr. Willis, received such remunerations. Save for one conclusory allegation that "Defendant engaged Dr. Willis in a phony clinical trial respecting Rebetron Combination Therapy beginning shortly after the August 2001 FDA approval letter issued**,"** (MAC, ¶ 93.), Dr. Willis is not mentioned as involved at all in the activities identified as practices intended to encourage providers to prescribe Subject Drugs to patients "despite the fact that no treatment was needed and despite availability of less expensive, alternative courses of treatment." (Id., ¶ 76.) Granted, the Court must assume the truth of fact asserted, and thus credits the allegation that Dr. Willis was involved in a clinical trial. It need not, however, credit the bald assertion that the trial was "phony," presumably meaning that Dr. Willis was not actually gathering data and studying patients taking the combination therapy or that he was but only as subterfuge for collecting incentive payments from Schering for prescribing the drugs being studied. Morse v. Lower Merion School Dist., 132 F.3d 902, 906 (3d Cir.1997) (holding that Court reviewing a complaint need not credit its "bald assertions" or "legal conclusions"). Nothing in the Amended Complaint supports this characterization.

Plaintiff apparently believes that somehow, through the incorporation of allegations made in other proceedings, such as the False Claims Act action filed by three qui tam relators, she can pursue her own relief against Schering. The irreducible minimum of Article III standing, however, requires Montgomery to demonstrate that she, personally, has suffered a concrete injury, that her injury can be traced to Schering's misconduct and that it is capable of redress by the Court. Assuming Schering engaged in all of the marketing practices detailed in Montgomery's Amended Complaint and in documents incorporated by reference, and assuming

that the practices might be deemed unlawful, none of the factual allegations she makes establish the required nexus between her injury and Schering's actions. The information contained in Montgomery's medical records, which the Court has properly considered as they are referenced in the Amended Complaint, underscore that it is hardly a foregone conclusion that Dr. Willis's revised treatment plan must be attributable to some nefarious influence or interference by Schering. Far from plausible, the asserted link is based purely on speculation and suspicion.

As the Court has clarified in the accompanying Opinion relating to Schering's motion to dismiss the Amended Complaint filed by the third-party payor Plaintiffs, the Court does not intend the dismissal of Montgomery's Amended Complaint to equate with its imprimatur of Schering's marketing practices as they are described in the pleading. The Court's role, however, is not to offer advisory opinions about conduct which may or may not be lawful or ethical. It is to adjudicate the rights as between the parties to a particular and circumscribed lawsuit. Without some threshold showing that one party's legal interests have been invaded by the conduct of the adversarial party, the Court simply lacks authority to act.

III. CONCLUSION

For the reasons discussed above, Plaintiff has failed to demonstrate that she has standing to pursue this action. Accordingly, the action must be dismissed for lack of jurisdiction, pursuant to Rule 12(b)(1). An appropriate form of Order will be filed.

s/Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

DATED: June 9, 2010